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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/578,130

05/02/2006

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A013-5786 (PCT)

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07/18/2011

EXAMINER

HANRAHAN, BENEDICT L

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/578,130	<b>Applicant(s)</b> VON WEYMARN-SCHARLI, ALEXANDER	
	<b>Examiner</b> BENEDICT L C HANRAHAN	<b>Art Unit</b> 3761	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2011.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 10-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Claims Status***

1. Claims 1-9 and 22-29 are canceled, and claims 10-21 are examined on the merits.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whayne et al. (US 6,203,525; hereinafter Whayne) in view of Bai (US 4,619,643).
6. Regarding claims 10 and 11, Whayne discloses a device 10 (Fig 1) for at least partial introduction into a body passage, the device comprising: a long, outer envelope body 36 (Figs. 1, 8A and 8B); a long inner body 12 and 28 (Figs. 1, 8A and 8B) that is at least partially peripherally surrounded by the envelope body 36 (Figs. 1, 8A and 8B); and a control device 20 (Figs. 1, 8A and 8B) that enables and impedes relative movement between the envelope body and the inner body to respectively impart flexibility and rigidity to the entire device in a controllable manner (Col 10, lines 11-29); wherein the control device 20 (Figs. 1, 8A and 8B) is itself formed by the arrangement and embodiment of the envelope body 36 (Figs. 1, 8A and 8B) and the inner body 12 and 28 (Figs. 1, 8A and 8B) and comprises no additional mechanical means in an annular intermediate region (Fig 8B, space between outer body 36 and the inner body 28) between the envelope body 36 (Figs. 1, 8A and 8B) and the inner body 12 and 28 (Figs. 1, 8A and 8B); the material of the envelope body and the inner body is flexible yet torsionally resistant (Col 1, lines 46-49 and 55-60) and the envelope body and the inner body can be rotated

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relative to one another by the control device in such a way that the corners of the inner body make contact at least partially with an inner wall of the envelope body to impart greater rigidity to the envelope body (The shape of the inner and outer bodies impedes the coaxial rotational of the bodies relative to each other; Col 10, lines 11-29).

Wayne discloses that the geometry of the inner and outer body may be changed in order to prevent rotation (Col 10, lines 11-29) thus providing motivation and suggestion for different shapes, and an outer body with a hexagonal shape 36 (Fig 8B) but does not specifically disclose that the envelope body and the inner body have similarly-shaped polygonal cross sections.

However, Bai discloses a double lumen catheter that is in the same field of endeavor as Wayne's catheter and is easy to insert and withdraw and prevents blood clotting and buckling (Col 1, lines 26-32 and 55-62 and Col 3, lines 8-19) where the inner and outer bodies have a polygonal cross section and the corners are lined up as shown in Figures 3c - 3e. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the Wayne's reference, to include a polygonal cross section, as suggested and taught by Bai, for the purpose of making the outer body as small possible while still imparting structural rigidity so as to make insertion easy but prevent the chance of buckling. Wayne and Bai do not specifically disclose a hexagonal cross section on the inner and outer body. The combination of Wayne and Bai disclose a cross section with three sides on both bodies and a hexagonal shape on the outer body but do not disclose six sides on both the inner and outer body. It would be obvious to one skilled in the art at the time of the invention that six sides may have been used instead of three to impart structural rigidity, ease insertion of the device, and allow the shape of the outer configuration to adapt to different geometries within a body region as Wayne has

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disclosed using similar geometries on the inner and outer body (Whayne, Col 1, lines 46-49 and Col 10, lines 11-29). A change in form or shape is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955)

7. Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whayne et al. (US 6,203,525; hereinafter Whayne) in view of Bai (US 4,619,643) and in further view of Avellanet et al. (US 5,542,938; hereinafter Avellanet).

8. Regarding claims 12 and 14, Whayne discloses a control device 20 (Figs. 1, 8A and 8B) but does not specifically disclose the introduction of a pressure medium to the annular intermediate region between the envelope body and the inner body. However, Avellanet discloses a magnetic guidewire coupling for catheter exchange that has a balloon expanded by filling it with a liquid. The balloon is used to change the contour and geometry in the cardiovascular system (Fig 1A and Col 1, lines 21-25 and 54-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the Whayne's reference, to include liquid to be filled in a balloon, as suggested and taught by Avellanet, for the purpose of being able to contour the cardiovascular system in order to create lesions with the desired geometry and characteristics.

9. Regarding claims 13 and 15, Whayne discloses an envelope body 36 (Figs. 1, 8A and 8B) and an inner body 12 and 28 (Figs. 1, 8A and 8B) and the inner body having a magnetic coating 22 (Figs. 1, 8A and 8B) but does not specifically disclose that the envelope body has a magnetic coating. However, Avellanet discloses a catheter where the inner and outer body both have a magnetic coating in order to control their relative positioning to one another (Fig 1A-5 and Col 3, lines 44-54, Col 3, line 66 to Col 4, line 3 and Col 4, lines 37-40). Therefore, it would have been

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obvious to one of ordinary skill in the art at the time of invention was made to modify the Wayne's reference, to include a magnetic coating on the outer envelope body, as suggested and taught by Avellanet, for the purpose of being able to have better control of the catheter when it is positioned in the body, which will help increase the quality of lesions (Avellanet, Col 1, lines 46-49).

10. Claims 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wayne et al. (US 6,203,525; hereinafter Wayne) in view of Avellanet et al. (US 5,542,938; hereinafter Avellanet).

11. Regarding claim 16-17 and 20-21, Wayne discloses a device 10 (Fig 1) for at least partial introduction into a body passage, the device comprising: a long, outer envelope body 36 (Figs. 1, 8A and 8B); a long inner body 12 and 28 (Figs. 1, 8A and 8B) that is at least partially peripherally surrounded by the envelope body 36 (Figs. 1, 8A and 8B); and a control device 20 (Figs. 1, 8A and 8B) that enables and impedes relative movement between the envelope body and the inner body to respectively impart flexibility and rigidity to the entire device in a controllable manner (Col 10, lines 11-29); wherein the control device 20 (Figs. 1, 8A and 8B) is formed by the arrangement and embodiment of the envelope body 36 (Figs. 1, 8A and 8B) and the inner body 12 and 28 (Figs. 1, 8A and 8B) and comprises no additional mechanical means in an annular intermediate region (Fig 8B, space between outer body 36 and the inner body 28) between the envelope body 36 (Figs. 1, 8A and 8B) and the inner body 12 and 28 (Figs. 1, 8A and 8B). Wayne discloses the inner body having a magnetic coating 22 (Figs. 1, 8A and 8B) and the application of an electrical voltage (Col 5, lines 53-59).

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Wayne does not disclose that the control device and the envelope body and the inner body are embodied in such a way that magnetic fields of different polarity can be alternately generated along the length of the envelope body and along the length of the inner body for the selective production of a mutual attraction of the two bodies at a location within the body passage. However, Avellanet discloses a catheter where the inner and outer body both have a magnetic coating in order to control their relative positioning to one another (Fig 1A-5 and Col 3, lines 44-54, Col 3, line 66 to Col 4, line 3 and Col 4, lines 37-40). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the Wayne's reference, to include a magnetic coating on the outer envelope body, as suggested and taught by Avellanet, for the purpose of being able to have better control of the catheter when it is positioned in the body, which will help increase the quality of lesions (Avellanet, Col 1, lines 46-49).

12. Regarding claim 18, Wayne discloses a control device 20 (Figs. 1, 8A and 8B) but does not specifically disclose the introduction of a pressure medium to the annular intermediate region between the envelope body and the inner body. However, Avellanet discloses a magnetic guidewire coupling for catheter exchange that has a balloon expanded by filling it with a liquid. The balloon is used to change the contour and geometry in the cardiovascular system (Fig 1A-5 and Col 1, lines 21-25 and 54-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the Wayne's reference, to include liquid to be filled in a balloon, as suggested and taught by Avellanet, for the purpose of being able to contour the cardiovascular system in order to create lesions with the desired geometry and characteristics.

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13. Regarding claim 19, Whayne discloses an envelope body 36 (Figs. 1, 8A and 8B) and an inner body 12 and 28 (Figs. 1, 8A and 8B) and the inner body having a magnetic coating 22 (Figs. 1, 8A and 8B) but does not specifically disclose that the envelope body has a magnetic coating. However, Avellanet discloses a catheter where the inner and outer body both have a magnetic coating in order to control their relative positioning to one another (Fig 1A-5 and Col 3, lines 44-54, Col 3, line 66 to Col 4, line 3 and Col 4, lines 37-40). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the Whayne's reference, to include a magnetic coating on the outer envelope body, as suggested and taught by Avellanet, for the purpose of being able to have better control of the catheter when it is positioned in the body, which will help increase the quality of lesions (Avellanet, Col 1, lines 46-49).

#### ***Response to Arguments***

14. Applicant's arguments filed 4/20/2011 have been fully considered but they are not persuasive.

Applicant argues that the limited rotation between the outer envelope body 36 and inner body 12 and 28 of Whayne does not impart greater rigidity (Whayne, Col 10, lines 11-29).

Examiner respectfully disagrees. Once the two bodies are rotated so that they can no longer rotate anymore, they will provide greater rigidity. There will be two bodies providing structural rigidity instead of just one.

Applicant argues that the control device 20 of Whayne is to be used to function to sense electrical events and not to controllably impart flexibility and rigidity. Examiner respectfully disagrees. A device can have more than one function. The control device can sense electrical

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events and also controllably impart flexibility and rigidity. Please also MPEP 2114 regarding the manner of operating device.

Applicant argues that Wayne does not disclose that the envelope body and the inner body have similarly shaped polygonal cross sections. Examiner respectfully disagrees. Wayne is not relied to disclose the polygonal shape. However, Wayne does disclose that the geometries of outer envelope body 36 and inner body 28 may be similarly shaped to controllably for a prescribed range of motion (Col 6, lines 1-5 and Col 10, lines 24-26). Furthermore, Fig 8B shows the outer envelope body 36 has a polygonal cross section.

Applicant argues that Bai shows the outer and inner bodies are rotationally rigid with respect to one another. Examiner respectfully disagrees with this argument. Bai is not combined with Wayne to show that the outer and inner bodies can be rotated with respect to one another. Bai is combined with Wayne to show polygonal cross sections that are similarly shaped for the inner and outer body (Wayne, Figs. 3c-3e). Wayne discloses that the bodies may be similarly shaped to impart a prescribed range of motion and Bai discloses that the bodies may have a polygonal cross section.

Applicant argues that there is no motivation to combine Bai and Wayne. Examiner respectfully disagrees. Bai and Wayne are in the same field of endeavor: an insertable catheter with an inner and outer body in order to control movement

Applicant argues that Bai and Wayne do not disclose a hexagonal cross section for both bodies and that Examiner relies on Applicant's disclosure for motivation. Examiner respectfully disagrees. Applicant has not addressed Examiner's arguments that Wayne discloses hexagonal cross section for the outer body 36 (Fig 8B). Wayne also discloses the inner and outer bodies

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may be matched (Col 10, lines 24-26). Bai discloses a three sided polygonal cross sectional but not six. Examiner relies on the teaching of Whayne's six sided body 36 (Fig 8B) and Whayne and Bai's disclosure for matching inner and outer bodies to disclose a hexagonal cross section for the inner and outer bodies.

Applicant argues that Whayne and Avellanet are not combinable. Examiner respectfully disagrees. They are in the same field of endeavor, insertable catheters, and directed to a same problem, controlling the movement of a catheter.

Applicant argues the Avellanet's magnetic fields of attraction are not generated at a location within the body passage and bases arguments on magnet 22 as shown in Figure 1. Examiner respectfully disagrees. Examiner relies on Fig 1A, which shows the magnet 22' before the holding attachment and can therefore be located in the body passage. Furthermore, Applicant has not specified what body passage is to be used. Some body passages are larger than other body passages. Body passages differ in size from person to the next. Also, the body passage may have been made by a surgical tool, which would allow large objects to pass through.

Applicant argues that Avellanet does not disclose the use of the magnets to impede movement. Examiner respectfully disagrees. Avellanet discloses a magnetic force may be applied to inhibit motion (Col 3, lines 44-54).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENEDICT L C HANRAHAN whose telephone number is (571)270-7854. The examiner can normally be reached on Monday-Friday, 8AM-5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/B. L. H./

Examiner, Art Unit 3761

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit  
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